Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221
September 29, 2003

Mr. Michael C. Eagle
U.S. Environmental Protection Agency
Office of Radiation Protection and Indoor Air
Radiation Protection Division
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

Dear Mr. Eagle:

Please be advised that a team of auditors from the Carlsbad Field Office will conduct a surveillance at Los Alamos National Laboratory on October 28 through October 30, 2003. The surveillance will evaluate the adequacy, implementation, and effectiveness of the Sealed Source Peer Review process for determining if the qualified existing radiological data for sealed sources is a suitable alternative to NDA measurements in meeting the data quality objectives set forth in the CH WAC. The surveillance will be conducted in accordance with the enclosed surveillance plan.

If you have any questions or comments concerning the surveillance, please contact me at (505) 234-7442.

Sincerely,

M. Lea Chism

M. Lea Chism
Quality Assurance Specialist

Enclosure

cc: w/enclosure
A. Holland, CBFO *ED
K. Watson, CBFO *ED
B. Shroff, EPA *ED
R. Joglekar, EPA *ED
E. Feltcorn, EPA *ED
M. Rojo, CTAC *ED
L. Greene, WRES *ED
K. Dunbar, WRES
CBFO QA File
CBFO M&RC

*ED denotes electronic distribution
CBFO:QA:MLC:GS:03-2589:UFC 2300.00

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CARLSBAD FIELD OFFICE SURVEILLANCE PLAN

Surveillance Number: CBFO S-04-05

Organization to Be Surveilled: Los Alamos National Laboratory (LANL)

Organizations to Be Notified: Los Alamos National Laboratory (LANL)
Environmental Protection Agency (EPA)
Environmental Evaluation Group (EEG)

Date and Location: October 28 to October 30, 2003
Los Alamos, New Mexico

Surveillance Team:

J. Gray	Surveillance Team Leader, CTAC
A. Arceo	Surveillance Team Member, CTAC

Surveillance Scope:

The surveillance will evaluate the adequacy, implementation, and effectiveness of the Sealed Source Peer Review process for determining if the qualified existing radiological data for sealed sources is a suitable alternative to NDA measurements in meeting the data quality objectives set forth in the CH WAC.

Activities:

The following peer review process elements will be evaluated:

- Applicability of the peer review
- Structure of the peer review group
- Acceptability of peer review group members
- Peer review process and reporting

Governing Documents/Requirements:

Adequacy evaluations of the peer review process and the surveillance checklists will be based upon the following documents:

- Sealed Source Peer Review Program Plan, Revision 0, September 16, 2003. (Attached)

- NRC (U.S. Nuclear Regulatory Commission), 1988, Peer review for High-level Nuclear Waste Repositories, General Technical Position, NUREG 1297, February 1988.

Schedule of Audit Activities:

A pre-surveillance conference is scheduled for 8:00 a.m. Tuesday, October 28, 2003, in the designated area at LANL.

A post-surveillance conference is scheduled for Thursday, October 30, 2003, in the designated area at LANL.

Prepared By: _____ Date: 9/25/03
John Gray, Surveillance Team Leader

Approved By: _____ Date: 9/25/03
Ava L. Holland,
CBFO Quality Assurance Manager

ATTACHMENT
Sealed Source Peer Review Program Plan

SEALED SOURCE PEER REVIEW PLAN

This plan describes the process and documentation requirements for the use of the peer review process to qualify existing data for sealed radiological sources in lieu of performing radioassay. The peer review process will be performed in accordance with criteria provided in 40 CFR § 194.22 which specifies the use of the NUREG 1297 guidelines. The plan defines the management approach, resources, schedule, and technical requirements for the subject peer review.

BACKGROUND

Sealed sources are known quantities of radioactive materials that have been encapuslated in quantities that produce known radiation fields. Sealed sources have multiple uses ranging from instrument calibration sources to sources that produce radiation fields for experimental applications. The Off-Site Source Recovery (OSR) Project at Los Alamos National Laboratory (LANL), created in 1999, under the direction of the Waste Management Division of the U.S. Department of Energy (DOE) Albuquerque has been assigned the responsibility to recover and manage excess and unwanted radioactive sealed sources from the public and private sector. LANL intends to ship drums containing qualified sealed sources to the Waste Isolation Pilot Plant (WIPP) for disposal. Prior to shipping, these drums must be characterized with respect to radiological content and other parameters. The U. S. Environmental Protection Agency (EPA) requires that ten radionulcides be quantified and reported for every container of waste to be disposed in the WIPP. The methods traditionally approved by the EPA include non-destructive assay (NDA) in accordance with Appendix A of the *Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant* (DOE, 2002) (CH WAC). However, because of the nature and pedigree of historical records for sealed sources and the technical infeasibility of performing NDA on these sources, LANL proposes to characterize the content of these waste drums using qualified existing radiological data in lieu of direct measurement.

The use of qualified existing data is allowed by the EPA under 40 CFR 194.22 as long as the data were collected under an Nuclear Quality Assurance (NQA) program (40 CFR § 194.22(a)) or if not collected under an approved NQA program the data are qualified using one or more of the following alternative methods (40 CFR § 194.22 (b)):

Determination that the data were collected under a QA program that is equivalent in effect to ASME NQA-1-1989 edition; ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition; and NQA-3-1989

The use of corroborating data, with the data relationships and inferences clearly identified and justified

Confirmatory testing that is performed and documented

- Peer review conducted in a manner that is compatible with NUREG-1297, *Peer Review for High Level Nuclear Waste Repositories.*

Based on the viability of each alternative for qulaifying existing data, performing a peer review is the most suitable. The peer review process uses a documented critical review, performed by

peers who possess qualifications at least equal to those of the individuals who conducted the original work. The peer reviewers will be independent of the work being reviewed. This means that the peer reviewer a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to ensure the work is impartially reviewed.

A peer review of a subject matter results in assurance to the regulator and the public that the subject matter is reasonable, accurate and valid for its intended use.

SCOPE OF THE PEER REVIEW

The Sealed Source Peer Review will determine if the qualified existing data is a suitable alternative to NDA measurements in meeting the data quality objectives set forth in the CH WAC. The scope of this peer review is limited to assessing the quality of historical radiological records and the analysis of this historical information as it is used to characterize actinide (predominately Pu-239, Pu-238 and Am-241) bearing sealed sources, destined for disposal at WIPP.

The peer review shall be performed in a manner that is compatible with NUREG 1297, as required by 40 CFR § 194.27(b). In general, the peer review process will analyze and evaluate (a) validity of assumptions; (b) alternate interpretations; (c) uncertainty of results and consequences if wrong; (d) appropriateness and limitations of methodology and procedures; (e) adequacy of application; (f) accuracy of calculations; (g) validity of conclusions; and (h) adequacy of requirements and criteria.

Specifically, the peer review will provide answers to the following technical questions:

- Source of radionuclide material
  - Is there sufficient documentation of sealed sources origin/history related to specific sealed sources to specific quantities of radioactive materials?
  - Is there sufficient documentation of the production of the source material to model isotopic distributions?
- Sealed Source Manufacture
  - Are the existing radiological data and historical records accurate and complete?
  - Does the documentation allow the determination of the default nuclide distributions and the uncertainties associated with the distributions?

Determination of Isotopic Distribution

Do source configurations/markings/documentation demonstrate that no modification of the source material has occurred?

Is the method for determining the isotopic distribution based on source materials identified in manufacture records appropriate for the source material?

Acceptability of the Characterization Approach.

- Are the records accurate and complete?

Is the overall characterization program for determining the required radionuclide distribution adequate for meeting the data quality objectives in the CH WAC?

The following items are outside the scope of the peer review:

Radiological characterization requirments not associated with WIPP's EPA Certification

- Non radiological characterization parameters and techniques
- AK records for sources not WIPP eligible

DESCRIPTION OF THE WORK TO BE REVIEWED

The peer review will evaluate the use of AK records and standard isotopic modeling to define the 10 radionuclides specified by the EPA and the associated uncertainties. The peer review will look at the program and the documented criteria for identifying and selecting which existing data are considered acceptable, either alone or in combination with other records for meeting the data qualtiy objectives. The review will evaluate actual AK records compiled for WIPP eligible sources and determine if the process for ensuring the quality of these records is suitable for future sealed sources that have not yet been determined to be WIPP eligible. The peer review will evaluate AK information from various references, such as the U.S. Nuclear Regulatory Commission (NRC) registry of sealed sources, the sealed source manufacturer, the original shipping paper and specification sheet, and data from the NRC/U.S. Department of Energy (DOE) Nuclear Material Management and Safeguards System (NMMSS), as well as other physical information about the sealed source.

The peer review will evaluate the proposed analytical methods for taking the acceptable AK data and estimating the nuclide distribution and content for all ten EPA-required radionuclides as specified in the CH WAC for individual sources and disposal containers. The characterization method will provide corrections for radiological decay, activation, and transmutation products. Assumptions and inputs to the software and the resulting output and uncertainty calculations will be reviewed as part of the peer review.

COMPOSITION OF THE PEER REVIEW PANEL

Members of the Sealed Sources Peer Review Panel (SSPRP) will represent the appropriate spectrum of knowledge and experience regarding sealed sources and WIPP disposal requirements. Each peer reviewer will have recognized and verifiable credentials in the technical area he or she is selected to evaluate. The collective technical expertise and qualifications of the peer group members will span the issues and areas involved in qualifying the historical data and the process for collecting and using these data for sealed sources, including but not limited to the below expertise:

Source production

- Source material production

Source useage

WIPP characterization program

Health physics (including statistics and radiological modeling)

- NDA

Regulatory Oversight

Technical areas more central to the work to be reviewed (e.g., health physics, WIPP characterization program, source manufacturing) will receive proportionally more representation on the peer review panel. The peer review panel will be composed of a minimum of three individuals who possess the subject matter technical expertise to a degree at least equivalent to that needed for the original work.

A peer review chairperson will be appointed by the peer review manager based on the technical leadership. The chairperson, with assistance from the peer review manager, will determine the manner in which the required peer review evaluations will be conducted. He or she will coordinate assignments of specific review tasks and activities among the review panel.

Members of the peer review panel will be independent from the work being under review. They will have not participated in any capacity with the development of the work under review and be free from funding, administrative, and managerial ties to ensure the work is impartially reviewed. In cases where total independence cannot be met because someone of equivalent technical qualification and greater independence is not available, the rationale for the reviewer selection will be documented.

SCHEDULE

This schedule will serve as the baseline schedule from which requested schedule deviations will be evaluated by the peer review manager, if appropriate. Revisions to the baseline schedule will not require revision to this plan, but must be approved by the LANL OSR manager, or designee.

The Peer Review process will consist of the following milestones and deliverables:

Milestone /Deliverable	Date Due
Selection Committee Convenes	September 11, 2003
Peer Review Meeting Start	October 27, 2003
Peer Review Meeting End	October 31, 2003
Draft Meeting Reports/Minutes	Business day following meeting
Final Meeting Minutes	2nd business day after meeting
Internal Draft Peer Review Report	November 3, 2003
Comments on Internal Draft Report	November 5, 2003
External Draft Peer Review Report	November 10, 2003

Comments on External Draft	November 12, 2003
Final Peer Review Report	November 17, 2003
Peer Review QA File	November 26, 2003

PEER REVIEW PROCESS

The peer review process will closely follow the Attachment 1 of CBFO procedure MP 10.5, Peer Review, which is developed in accordance with and implements the guidance in NUREG 1297. Specifically the peer review process will:

- Follow a written procedure. In the absence of a LANL-specific procedure, CBFO MP 10.5, Attachment 1 will be used. In the event of a conflict between the peer review procedure and NUREG 1297, NUREG 1297 will take precedence.
- Include documentation of the peer review. Activities include documenting the selection of panel members, assignment of a panel leader, panel member independence documentation, and recording and archiving meeting minutes.
- Be conducted in accordance with a schedule for the peer review established by the LANL OSR manager, or designee.
- Provide communication of interim peer review findings in hardcopy to the LANL OSR manager, or designee
- Produce a formal written report of the peer review findings and conclusions.
- Follow quality assurance (QA) requirements for document preparation, control and records archiving.

Mr. Ron Burns of Washington Safety Management Solutions will serve as the Peer Review Manager.

Mr. Lee Leonard of LANL will serve as the LANL OSR Manager. Mr. Jerry McAlpin will serve as the primary designee for the LANL OSR Manager. Other LANL OSR staff will serve as technical advisors. The cognizant LANL OSR Manager, or designee, is responsible for the peer review.

A selection committee consisting of two individuals in addition to the peer review manager will select candidates for the peer review panel. Upon verification that the SSPRP members meet the criteria outlined in MP 10.5, Attachment 1, sealed source orientation and training will be scheduled as part of the first day of the SSPRP review meetings. The SSPRP members are expected to complete their review of required reading materials prior to the orientation meeting.

Throughout the review, the SSPRP is encouraged to engage in frank discussions with the individuals responsible for the work under review. However, the SSPRP must observe all rules for interaction with EPA, CBFO, LANL, and stakeholders, as outlined in MP 10.5.

Adequacy Criteria

The quality of existing radiological data, as well as the overall proposed characterization method mus meet commonly accepted technical and scientific standards based on the in-depth evaluation afforde by the peer review process. The SSPRP will perform their review using the adequacy criteria in NUREG 1297 as a guide for their review. The criteria in NUREG 1297 are as follows:

Validity of assumptions,

- Alternate interpretations,
- Uncertainty of results and consequences if the model is inadequate,

Appropriateness and limitations of methodology and procedures,

- Adequacy of application,
- Accuracy of calculations,

Validity of conclusions, and

- Adequacy of requirements and criteria.

Additional criteria may be defined by the panel.

Report

The SSPRP chairperson, with the assistance of the peer review manager, will ensure that the SSPRP findings are formally documented in a report. At the request of the LANL OSR Manage or designee, a draft of this report may be provided prior to finalization. However, to ensure the independence of the panel's conclusions, transmittal copy and any subsequent comments are for information only.

The SSPRP report shall:

A. Be signed by each SSPRP member

B. Describe the work or issue that was reviewed

C. Describe the conclusions reached by the SSPRP

D. Provide individual statements by the SSPRP members reflecting dissenting views or additional comments, as appropriate

E. List the SSPRP members and provide acceptability information (i.e., technical qualifications and independence) for each member including any potential technical and or organizational partiality

Daily Meetings

The peer review will consist of daily team meetings. The first day will be reserved for orientaio and background information, The second, third and fourth days will be technical evaluation of the proposed characteization and overall method. The agenda and review format will be determined by the SSPRP chairperson based on the needs of the SSPRP members and the availability of resources. With concurrence of the SSPRP chairperson, the SSPRP may chose t

break into smaller work sessions. At the end of each day the SSPRP will reconvene as a whole to summarize its activities. The peer review manager will ensure that written meeting minutes are developed, distributed to SSPRP members and are maintained as QA records. Authorization for observers to attend the daily meetings will be obtained through the peer review manager prior to admittance.

Peer Review Daily Caucus

At the conclusion of each day of peer review meetings the SSPRP chairperson will convene a peer review caucus to set the next day's agenda and address issues, concerns, questions, conflicts, etc. The peer review manager will assist the SSPRP chairperson in resolution of the issues discussed in the daily caucus, as necessary. The peer review manager will ensure that written caucus minutes are developed and will ensure the minutes are maintained as QA records. Authorization for observers to attend the caucus meetings will be obtained through the peer review manager prior to admittance.

Logistics

Required reading material necessary to support the peer review will be provided by the peer review manager, or designee, for distribution to the panel. The material will be briefly reviewed and open for discussion during the first day orientation sessions. It is assumed that the peer review will not need to be conduct in a phased manner because of the limited scope of the review. The peer review manager and the SSPRP chairperson will establish the basic review agenda for each day's session based on availability of technical staff, SSPRP member interests, and other factors discussed in the daily meetings and caucuses.

The peer review meetings will be held away from LANL or other government properties to avoid distractions of key technical resources and ensure independence from LANL influences. These meetings, although remote from LANL, will be held close enough where needed

made

Manager. No reasonable request will be refused.

QUALITY ASSURANCE

The peer review process will be conducted and documented in a controlled manner and in compliance with the Project 2010 Quality Assurance Program and applicable QA procedures.

The QA Oversight Manager will conduct assessments of the peer review process to ensure that all aspects of the peer review conform to NUREG 1297. Paul Bell of Washington Group International will serve as the QA Oversight Manager. The QA Oversight Manager will present any assessment findings to the peer review manager. The QA Oversight Manager will review the resolution of any findings to ensure that they include an assessment of the impact of the finding(s) on the ongoing peer review

The Project 2010 QA Manager may appoint observers to attend the peer review orientation and peer

review meetings. The Project 2010 OSR QA Manager may schedule an assessment or audit of the peer review process and records prior to completion of the review.

Records generated as a result of sealed sources peer review activities defined in this peer review plan and Attachment 1 of MP 10.5 will be designated as QA records and maintained by the peer review manager in accordance with Project 2010 QA Program until after the final peer review report is issued and the peer review process is completed. Duplicate records shall be generated and maintained at separate facilities. Upon completion of the peer review process, the original copy of the QA records (when possible) shall be formally transferred and delivered to the LANL OSR Manager, or designee, for retention. QA records to be retained include:

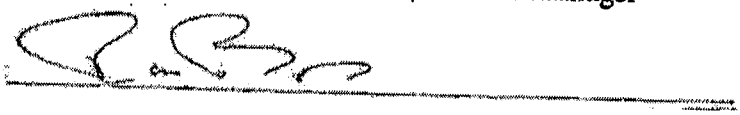
A. Peer review plan
B. Peer review procedure(s), if applicable.
C. Service acquisition document(s)
D. SSPRP member verification of education/employment documentation
E. Determination of SSPRP member independence documentation
F. SSPRP member selection justification/decision documentation
G. SSPRP member service provider contracting documentation
H. Observer inquiry forms
I. SSPRP chairperson qualification documentation
J. SSPRP member selection documentation
K. SSPRP orientation documentation and attendance form
L. Written minutes of meetings, deliberations, and activities
M. Sealed sources peer review report.

An invitation will be extended to the EPA and the CBFO to observe the sealed sources peer review process.

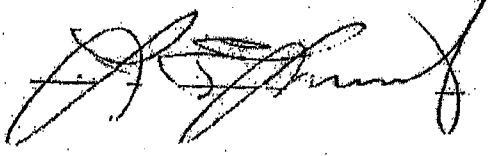
APPROVAL

This Peer Review Plan is submitted to the cognizant LANL OSR Manager, or designee, for approval.

Prepared by Ron Burns, Sealed Source Peer Review Manager

Signature 

Approved by Lee Leonard, LANL OSR Sealed Source Manager, or designee

Signature 

REFERENCES

DOE (U.S. Department of Energy), 2001. Peer Review, CBFO Management Procedure MP 10.5, Revision 3, November 15, 2001.

DOE (U.S. Department of Energy), 2002. Contact Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-02-3122, U.S. Department of Energy, Carlsbad Field Office, Carlsbad, NM.

NRC (U.S. Nuclear Regulatory Commission), 1988. Peer Review for High-level Nuclear Waste Repositories, General Technical Position, NUREG 1297, February 1988.

40 Code of Federal Regulations 194, Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations.